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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

MEDICAL DEVICES

Establishment Registration and Premarket Notification Procedures

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER H—MEDICAL DEVICES

[Docket No. 76N–0355]

ESTABLISHMENT REGISTRATION AND PREMARKET NOTIFICATION PROCEDURES

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The agency is issuing final regulations setting forth procedures for the registration of establishments in which devices intended for human use are produced. These regulations also establish requirements governing the form and manner in which premarket notification submissions are to be sent to the Food and Drug Administration (FDA), at least 90 days in advance, by any person who proposes to begin commercial distribution of a device intended for human use in interstate commerce. The Medical Device Amendments of 1976 have provided the agency with the authority to promulgate such regulations to ensure the safety and effectiveness of medical devices for humans.

The agency also is establishing rules governing the availability to the public of premarket notification submissions. The existence of a submission and its contents will generally be available to the public upon request, but the regulations provide an exception allowing the existence and contents of certain submissions to be considered confidential commercial information. However, the Commissioner announces his intention to consider further revisions in the regulation when he publishes proposed regulations concerning. FDA's handling of public information requests involving new drug applications and related industry submissions to FDA.

EFFECTIVE DATE: September 22, 1977.

FOR FURTHER INFORMATION CONTACT:

FOR THE ESTABLISHMENT REGISTRATION PROVISIONS

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FOR PREMARKET NOTIFICATION PROCEDURES

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SUPPLEMENTARY INFORMATION: The proposed regulations on which these final regulations are based were published in the FEDERAL REGISTER of September 3, 1976 (41 FR 37458). Interested persons were given until November 2, 1976 to comment.

Forty-seven comments were received on the proposal. The issues most often raised by these comments concerned the exemptions from registration, the requirements for submitting a premarket notification when a change or modification is made to a device already on the market, the FDA review of premarket notification submissions, and the confidentiality of premarket notification submissions.

In general, the final regulation has been adopted as proposed although several changes have been made in response to the comments and to clarify the language of the regulation.

ESTABLISHMENT REGISTRATION

1. Definitions of "act" and "distributor" are being added for clarity to § 807.3 of the final regulation. The Commissioner of Food and Drugs is also adding a new paragraph (h) to this section which states that the terms defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) shall have the same meaning in these registration regulations.

2. Three comments asserted that if the definition of "commercial distribution" was adopted as proposed in § 807.3 (a), multinational corporations would be required to file a premarket notification submission for an intraorganizational shipment between a foreign subsidiary and a domestic parent. The comments indicated that premarket notification in such a situation would not serve any useful purpose since the device will not go "on the market" at that point, and also indicated that a second premarket notification would be required when the device is about to be marketed by the parent company. It was therefore suggested that the words "registered domestic" should be deleted from the definition of "commercial distribution" to clarify that premarket notification is not required for such intraorganizational shipments.

The Commissioner agrees that premarket notification is not required when a device is to be shipped from a foreign subsidiary to a domestic parent establishment and there is no distribution outside the company. It is necessary, however, that FDA be notified at least 90 days before the device is distributed and held or offered for sale within the United States. Therefore, as suggested by the comments, the phrase "registered domestic" has been deleted from the definition of commercial distribution in the final regulation.

Two comments also suggested that the shipment of a device for display as a work-in-process or as an engineering prototype at a scientific exhibit should not be considered "commercial distribution" of a device. These comments noted that such shipments are useful to manufacturers and the scientific community and present no danger to the public health.

The Commissioner notes that the definition of "commercial distribution" applies only to a device that is "held or offered for sale." If a device is shipped merely for display as a work-in-process or as an engineering prototype at a scientific exhibit and is not held or offered for sale, it will not be considered to be in "commercial distribution."

3. One comment questioned whether the term "establishment" in proposed § 807.3(b) (redesignated § 807.3(c)) is synonymous with the terms "division" or "owner or operator." Another comment questioned whether a division of a company would be an "owner or operator" where such a division has more than one operating facility.

The Commissioner notes that an "establishment" within the meaning of new § 807.3(c) is a place of business at which a device is processed, whereas an "owner or operator" within the meaning of new § 807.3(f) is the person or organization directly responsible for the activities of an establishment. Therefore, the terms "establishment" and "owner or operator" are not synonymous. A division may be either an "establishment" or an "owner or operator" depending upon which definition applies.

4. One comment objected that proposed § 807.20 would require a manufacturer of a device "intended for human use" to register. This comment asserted that the phrase "intended for human use" is too broad and would include devices not within the scope of the act. The comment suggested that this phrase should be changed to "device as defined in section 201(h) of the act."

The Commissioner notes that the definition of device in section 201(h) of the act includes devices other than those intended for human use. However, the registration provisions of section 510 of the act (21 U.S.C. 360) and Part 807 apply only to devices intended for human use and not to devices intended for veterinary use. In all other respects the term "device" as used in the regulation is intended to carry the meaning conveyed in section 201(h) of the act. Therefore, the phrase "intended for human use" has been retained in the final regulation.

5. One comment objected to the fact that under proposed § 807.20(a) registration is required for any person who initiates specifications for a device that is to be manufactured for him for subsequent commercial distribution. It was argued that section 510 of the act requires the registration of any esablishment engaged in the manufacture, preparation, propagation, compounding, or processing of a device, and that the initiation of specifications is not within any of these processes.

The Commissioner believes that a person initiating specifications for a device to be manufactured for him for commercial distribution would be engaged both in the manufacture and in the propagation of a device and therefore should register with FDA. The initiation of specifications is a process that often occurs within the manufacturing establishment as part of the manufacturing process. A device may be manufactured exactly according to specifications and still be defective if the specifications are

faulty; for that reason, the regulation requires registration.

The Commissioner notes, however, that the requirement to register applies only if the person initiating specifications has the device manufactured for him for commercial distribution and the device is marketed under the name of the person initiating the specifications. The Commissioner believes that a person who has a device marketed under his name is engaged in the propagation of a device. The requirement to register does not apply when the person initiating the specifications is in a consulting capacity or transfers the rights to manufacture and to distribute the device to other persons. To reflect this position, the regulation has been changed in §§ 807.3(d)(3) and 807.20(a)(1) to provide that a person initiating specifications is required to register only if the device is to be put in commercial distribution by him.

6. One comment suggested that proposed § 807.20(a) be clarified so that only one establishment of a company would be required to register for each device and the manufacturer could determine which location would be the most appropriate one to register.

The suggestion has not been adopted. A device may be processed wholly or in part at more than one establishment. For the purposes of inspection, the Commissioner should be aware of all establishments at which a device is manufactured, prepared, propagated, compounded, or processed, and therefore all such establishments must be registered.

7. Various comments addressed the time periods allowed for establishment registration under proposed § 807.21. This section provided that an establishment register within 15 days of receiving Form FD–2891 (Initial Registration of Device Establishment) if the establishment were currently engaged in an operation requiring registration. One comment suggested that this period be changed to 30 days and another suggested that it should be 60 days. Proposed § 807.21 also provided that an establishment register within 5 days after submitting a premarket notification if it had not been previously engaged in an operation requiring registration. One comment suggested that this period be changed to 15 days; another suggested that it should be 30 days.

All these comments argued that the longer time periods are necessary so that the registration form can go through the approval process within the business organization.

The Commissioner agrees with these comments, and the time frames for registration have been changed in the final regulation. He also notes that in 1976 FDA mailed registration forms to all human medical device establishments of which it had knowledge. Many establishments completed and returned these registration forms, while other establishments did not register, awaiting these final regulations. The Food and Drug Administration does not plan another mass mailing of registration forms, but will send individual forms to establishments that request them. The requirement that establishments currently engaged in an operation requiring registration must register within 15 days after receiving Form FD–2891 has been deleted from the final regulation as unnecessary. Establishments currently engaged in an operation requiring registration that have not yet registered must register within 30 days after the effective date of this regulation.

The Commissioner has also determined that it is inappropriate to require an establishment not currently engaged in an operation requiring registration to register within 5 days after submitting a premarket modification. If the Commissioner determines that the device is not substantially equivalent to one already on the market and therefore premarket approval is required, the owner or operator may decide that it is not economically feasible to market the device. This would result in an establishment being registered that is not engaged in the medical device business. As a result, the final regulation requires the owner or operator to register within 30 days after entering into an operation requiring registration.

8. One comment suggested that Form FD–2891 (Initial Registration of Device Establishment) provide a space for designation of the person(s) to whom copies of correspondence should be sent. The comment stated that if a subcontract-manufacturer registers, there should be an official means of notifying the responsible manufacturer.

The Commissioner notes that under these regulations copies of all correspondence will be sent to the official correspondent as listed on Form FD–2891. The official correspondent is responsible for notifying the proper persons within the establishment, and, when desired by those persons, those with whom a contractual relationship exists.

9. Five comments argued that the 5-day period allowed for submission of amendments to the establishment registration under proposed § 807.26 is too short to allow for preparation within the company and for mailing time. Two of the comments suggested that the period should be 15 days; three comments suggested that 30 days should be allowed for submission of amendments.

The Commissioner agrees that 5 days may not be a sufficient time for submission of amendments to the registration form. The final regulation therefore allows 30 days for submission of an amendment after the change in registration information occurs.

10. One comment referring to proposed § 807.37 asserted that the establishment registration forms should not be made available for public inspection since the listing of device activities on them could be used to the disadvantage of the person submitting the registration forms.

Section 510(f) of the act requires the Commissioner to make available for public inspection any registration submitted pursuant to section 510. Accordingly, such information will be made available as required under the act. The Commissioner advises, however, that he does not believe that the registration forms require the submission of any trade secret information or any information that truly could be considered to be of a confidential commercial character.

11. Two comments sought clarification of the meaning of the word "requested" in proposed § 807.40 in reference to registration procedures for foreign device establishments. These comments asserted that if foreign manufacturers were not required to register it would give them an unfair competitive advantage over domestic manufacturers.

Section 510(i) of the act provides that foreign device establishments "shall be permitted" to register according to regulations to be promulgated by the Commissioner. The Commissioner therefore cannot as a matter of law require foreign device establishments to register. However, foreign device establishments will be required to list their devices with FDA in accordance with device-listing regulations that will be published in the FEDERAL REGISTER as a proposal in the near future.

Under section 801(a) of the act, the Commissioner is required to furnish the Secretary of the Treasury a list of foreign establishments registered pursuant to subsection 510(i). If a foreign manufacturer does not register under subsection 510(i) of the act or does not provide product-listing information under subsection 510(j) of the act, the device is required to be sampled by the Secretary of the Treasury for examination by FDA upon importation or an offer of importation into the United States.

12. One comment objected to the exemption in proposed § 807.65(d) for licensed practitioners who manufacture or alter devices solely for use in their practice. The comment stated that users who alter in vitro diagnostic products can create serious problems since such devices are no longer reporting results as labeled by the manufacturer.

The Commissioner advises that § 807.65(d) is intended to exempt licensed practitioners who manufacture, alter, or use devices to meet the needs of a particular patient; however, exemption from registration does not relieve such persons from their obligation to comply with other provisions of the act or regulations. The Commissioner believes that the problem of improper device use can be regulated more appropriately under the investigational device exemption authority of section 520(g) of the act (21 U.S.C. 360j(g)) and restricted device authority under section 520(e) of the act (21 U.S.C. 360j(e)). The comment is therefore rejected. The Commissioner recognizes that clinical laboratories, included in proposed § 807.65(d), generally provide a service resulting from the use of a device. He has therefore deleted reference to it in § 807.65(d), but has in-

corporated this exemption into new § 807.65(i).

13. One comment objected that proposed § 807.65(d) exempted from registration only licensed practitioners who alter devices. The comment noted that opticians are only licensed in 19 States and that no distinction should be made between licensed and unlicensed opticians where licensing is not available.

The Commissioner advises that opticians are specifically exempted in new § 807.65(i). The Commissioner intends this exemption to apply to any optician who meets the requirements to practice in the State in which he is practicing, whether or not there is a State licensing requirement.

14. One comment agreed that dental laboratories should be exempted from registration, but noted that in proposed § 807.65(i) they are exempted as persons who dispense devices to the ultimate consumer. The comment indicated that dental laboratories are forbidden by the Federal Denture Act of 1948 (18 U.S.C. 1821) to dispense devices to the ultimate consumer.

The final regulation has been rephrased to state that persons who dispense devices to the ultimate consumer or whose major responsibility is to render a service necessary to provide a consumer with a device are exempt from registration. In addition, the Commissioner is adding to the list of examples in § 807.65(i) assemblers of diagnostic X-ray systems. While such assemblers are exempt from registration, they continue to be subject to the assembler certification (reports of assembly) requirements in 21 CFR 1020.30(d).

15. One comment suggested that proposed § 807.65(i) be clarified to indicate that opticians who own and operate full-service laboratories should be exempted from establishment registration. These opticians perform functions such as processing, surfacing, edging, finishing, heat-treating, tempering, and assembling previously manufactured lenses or frames. The comment noted that these are the ordinary functions of opticians and it is therefore presumed that it was intended that opticians who perform these functions be exempted. Another comment noted that individuals and establishments that perform the same functions as full service optical laboratories are exempted by proposed §§ 807.65 (d) (licensed ophthalmologists and optometrists) and 807.65(i) (opticians). Additionally, two comments stated that the regulation should exempt all establishments engaged in the production of eyeglasses, except manufacturers of lens blanks and frames, since optometrists, opticians, and optical laboratories are not engaged in any process which involves a risk to the public health.

The Commissioner agrees with these comments, but does not believe that a change in the final regulation is necessary to reflect this position. While ophthalmologists, optometrists, and opticians are listed as examples of the types of individuals who are not required to register, the Commissioner believes that full service laboratories and similar establishments are exempted from registration. However, manufacturers of lens blanks and frames are not exempted and must register.

16. Comments suggested that proposed § 807.65 be clarified to indicate that a private labeler, who obtains a device from a manufacturer with the label already applied and who does not repackage or otherwise alter the container or label, is exempted from registration.

Paragraph (e) of this section provides an exemption for a pharmacy or similar retail establishment that purchases a device for subsequent distribution under its own name. The Commissioner intends this exemption to apply to a person who obtains a device from a manufacturer with the label already applied and who does not repackage the device or alter the container or label. The Commissioner believes that no change is necessary in the final regulation to reflect this position.

PREMARKET NOTIFICATION PROCEDURES

17. Comments asserted that FDA should not require a premarket notification submission when a person intends to reintroduce into commercial distribution a device that had once been in commercial distribution but had been subsequently discontinued. The comments stated that there is no legal or factual basis for such a requirement. One comment stated that there is nothing in the legislative history of section 510(k) of the act to substantiate the view that a discontinuance of commercial distribution before May 28, 1976, means that the device should not be considered to have been on the market prior to May 28, 1976. Another comment indicated that the House Report stated that section 510(k) of the act was "designed to insure that manufacturers do not intentionally circumvent the automatic classification of 'new' devices" (Medical Device Amendments of 1976, February 29, 1976, H.R. 94-853 at 37) and argued that this purpose would not be served by requiring a premarket notification submission for the reintroduction of a device on the market prior to May 28, 1976. An additional comment noted that no practical purpose would be served by this requirement since FDA would be notified of the reintroduction of any device under the device listing procedures of section 510(j) of the act.

The Commissioner generally agrees that it is not necessary to require a premarket notification submission for the resumption of commercial distribution of a device that was on the market and was later discontinued by the manufacturer. The owner or operator will, however, be required to report under the device listing regulations the resumption of commercial distribution of a device. The device listing regulations will be published in the FEDERAL REGISTER in the near future.

The owner or operator would not be circumventing the automatic classification of "new" devices if the device had previously been in commercial distribution and had been classified. The Commissioner cautions, however, that if the device in question has been changed or modified to the extent that a premarket notification would be required under the criteria of proposed § 807.81(a)(3), a premarket notification submission would then be required.

18. Numerous comments requested clarification or changes in proposed § 807.81(a)(3) with reference to situations requiring a premarket notification submission when a change or modification is to be made to a device already in commercial distribution. These comments stated that: (1) There is no need to require a premarket notification submission when a proposed change will increase the safety or effectiveness of the device. (2) Not every change in design, material, chemical composition, energy source, and manufacturing process is a significant change affecting the safety or effectiveness of the device and therefore a premarket notification submission should not be required for every such change. Instead, the regulation should identify what types of changes are significant enough to require a premarket notification submission. (3) The Food and Drug Administration should not require a premarket notification submission for every change in manufacturing process since too many such changes are made on a regular basis.

The Commissioner believes that FDA should be aware of and determine whether or not a change will increase the safety or effectiveness of the device. Proposed § 807.81(a)(3)(i), therefore, has been changed in the final regulation to require that a premarket notification be submitted only for changes that could significantly affect safety or effectiveness whether or not the manufacturer believes that it will increase or decrease safety or effectiveness.

The Commissioner did not intend that the owner or operator should submit a premarket notification for every change in design, material, chemical composition, energy source, or manufacturing process. This list was only intended as an example of some types of changes that often affect safety or effectiveness. The manufacturer is required to submit a premarket notification only if the change could significantly affect the safety or effectiveness of the device whether or not it is a change of one of the types given as examples. A change has been made in new § 807.81(a)(3) to indicate that premarket notification is required only if the change or modification could significantly affect the safety or effectiveness of the device or if there is a major change or modification in the intended use of the device.

Under the act, the burden is on the manufacturer to determine whether a premarket notification should be submitted for a change or modification in a device. The Commissioner believes that the manufacturer is the person best qualified to make this determination. If appropriate, FDA will notify the manu-

facturer that the premarket notification that was submitted need not have been submitted so that he may be aware that premarket notification is not required in such a situation. From such experiences, FDA may eventually draw some guidelines as to when a premarket notification submission is not required.

A question has been raised whether a premarket notification is required when a Firm B purchases the product line of a Company A, including the manufacturing facility for that product. The Commissioner believes that a premarket notification would not be required in that situation unless the devise has been changed or modified to the extent that the provisions of § 807.81(a)(3) would apply. Section 510(k) of the act would not apply to this situation because Firm B would not be proposing "to begin the introduction or delivery for introduction into interstate commerce for commercial distribution" of a device. Rather, Firm B would be marketing the device in place of Company A.

In such instances, FDA will be notified of a change in ownership by other means. Under new § 807.26, the owner or operator must report a change in individual owenrship or corporate or partnership structure within 30 days of the change. The owner or operator will also be required to report a change in ownership under the device-listing procedures to be published as proposed regulations in the FEDERAL REGISTER in the near future.

19. A comment objected that, under proposed § 807.85, the exemption from premarket notification to be granted to custom device manufacturers would not not be allowed if the device is offered through advertising by the manufacturer importer, or distributor. The comment noted that the dissemination of this information is essential to the medical community in obtaining the medical devices needed to treat all patients.

The prohibition of advertising in § 807.85 is intended to apply only to the advertising of a particular device. It does not prohibit the custom device manufacturer from advertising that he manufactures custom devices of a particular generic type. The exemption for manufacturers of custom devices is intended to apply to only those who are customizing devices to fit the needs of a particular patient so that they will not be required to file a premarket notification for each particular device. This reasoning does not apply if the manufacturer, through advertising, is generally offering a particular device for sale. If the device is widely offered through advertising, it could not be considered a custom device.

20. The Commissioner is adding to new § 807.85 exemptions from premarket notification for a distributor who places a device in commercial distribution for the first time under his own name and for a repackager who places his own name on a device, neither of whom otherwise changes the labeling or affects the device. The exemption applies if the device was in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976, and is being classified. If a premarket notification was submitted by another person, another premarket notification would be a duplication and would not be necessary.

21. One comment suggested that FDA exempt from the premarket notification requirements a device that has been changed by the manufacturer if (1) the device has the intended purpose of only performing in vitro diagnostic tests; (2) the change is intended to improve the device; and (3) the change does not require a change in labeling.

The Commission disagrees with the suggestion. A change can be made to an in vitro diagnostic product which does not require a change in labeling but that is significant enough to affect the safety and effectiveness of the device. Premarket notification must be required for such a change.

22. The Commissioner has also added to new § 807.87(a) a requirement that a premarket notification submission contain the classification name of the device, if known. This name is the one used by the classification panels in the classification process under section 513 of the act. Use of the classification name will be discussed further in the preamble to the proposed device-listing regulations, which will be published in the FEDERAL REGISTER in the near future. The Food and Drug Administration will furnish a list of classification names with the device-listing forms or upon request.

The Commissioner has added to new § 807.87(b) a requirement that a premarket notification submission contain the establishment registration number, if any, of the owner or operator submitting the premarket notification. This is to be used to identify registered manufacturers. The Food and Drug Administration will provide any person who does not supply an establishment registration number in the premarket notification with appropriate instructions on establishment registration.

The Commissioner has also added to new § 807.87(e) a requirement that a premarket notification include photographs or engineering drawings where applicable. Photographs or drawings should be submitted when they will aid in understanding the operation of the device.

23. One comment noted that proposed § 807.87(c) (redesignated § 807.87(d)) required that a premarket notification submission contain a statement of the action taken to comply with the premarket approval requirements of section 515 of the act, even though under proposed § 807.81(b) a premarket notification submission is not required when a premarket approval application has been submitted for the device.

The Commissioner agrees with this comment. If a premarket approval application has been submitted, a premarket notification submission would not be required since FDA would already be advised of the intent to market. Accordingly, the requirement has been deleted from the final regulation.

24. One comment objected that under proposed § 807.87 too much information is required to be included in a premarket notification submission. The comment asserted that section 510(k) of the act was intended to require notification only and not "mini-premarket approval."

The requirements of section 510(k) of the act are intended not only to notify FDA that a device is about to be marketed but primarily to enable FDA to determine whether the device is substantially equivalent to one already in commercial distribution. The information required by § 807.87 is necessary to carry out this purpose and is not intended to be a "mini-premarket approval application."

25. Several comments asserted that FDA has no authority for the requirement in proposed § 807.87(d) (redesignated § 807.87(e)) that representative advertisements be included in the premarket notification submission; the comments stated that under section 510(j)(1)(B) of the act, FDA may only require the submission of advertisements for restricted devices. One comment noted that advertisements may not yet be available 90 days before the marketing date.

The limiting procedures of section 510(j)(1)(B) of the act apply only to the listing of devices and therefore do not limit the authority of the Commissioner to require the submission of advertising with premarket notifications under section 510(k) of the act. Section 510(k) provides that premarket notification shall be submitted in such form and manner as the Commissioner shall by regulations prescribe. The Commissioner is of the opinion that this is authority for requiring the submission of representative advertisements. The submission of advertisements is necessary to show the uses for which a device is being promoted so as to determine whether the device is substantially equivalent to a device already in commercial distribution.

26. Several comments addressed proposed § 807.87(e) (redesignated § 807.87(f)) which requires the inclusion of a statement in the premarket notification submission indicating how a device is or is not substantially equivalent to a device already in commercial distribution and data to support that statement. One comment suggested that data to support the statement should be required only if necessary since, in many cases, it will be obvious if a device is substantially equivalent. Three comments suggested that FDA define more clearly the type of data needed to support a statement that a device is substantially equivalent. Also, one comment stated that it is not appropriate to require that supporting data be included in a premarket notification submission since section 510(k) of the act is a notification provision and not a premarket approval provision.

It has been pointed out above that submission of certain information is necessary to carry out the purpose of section 510(k) of the act. From the information submitted pursuant to section 510(k) of the act, the Commissioner must

be able to determine whether the device is substantially equivalent to one already in commercial distribution. The type of data needed to support a claim that one device is substantially equivalent to another will vary widely depending on the type of device. The Commissioner cannot make a more specific statement as to the type of information required. The information that is necessary must be determined on an individual basis. The manufacturer is best qualified to determine the type of information that should be submitted to demonstrate that his device is substantially equivalent to another device that was on the market on May 28, 1976 or is equivalent to a device that has been classified into class I or II.

The amount of data needed to support a claim of substantial equivalence also will vary widely. In some instances, the data needed to support claims of substantial equivalence will be minimal. The Commissioner therefore rejects the comments suggesting that supporting data only be required if necessary.

27. One comment objected that under proposed § 807.87(g) (redesignated § 807.87(h)), the owner or operator would have to wait an additional 90 days to market the device after submitting a new or amended premarket notification submission, when the Commissioner determines that the original submission was insufficient. The comment asserted that section 510(k) of the act does not provide for the approval or disapproval of a premarket notification submission and also does not contain any provisions that would allow the agency to keep a device off the market more than 90 days after the original filing of the premarket notification submission. One comment suggested that if the additional information requested for a premarket notification submission is submitted within 45 days of the original intended market date, the owner or operator should be allowed to market the device on the original date.

Several comments objected to the basic concept under proposed § 807.87(g) (now § 807.87(h)) that allows the Commissioner to request additional information from the owner or operator when there is insufficient information in the original premarket notification submission to determine whether the device is substantially equivalent to one already in commercial distribution. (Proposed § 807.87(g) also required that the requested information be submitted at least 90 days before the owner or operator intended to market the device.) Five comments noted that the preamble to the proposed regulation stated that the Commissioner would notify the owner or operator within 30 days if the information contained in the premarket notification submission was insufficient, but that no such statement was included in the regulation. Another comment stated that the regulation should require that FDA specify in its notification to the owner or operator exactly what information is lacking in the premarket notification submission.

As noted above, section 510(k) of the act is more than a notification provision. The Commissioner must determine whether the device about to be marketed is substantially equivalent to one already in commercial distribution. To this end, section 510(k) of the act provides that the notification shall be made in such form and manner as the Commissioner shall prescribe. The Commissioner therefore has the authority to reject a notification which does not meet the prescribed form or one which does not contain adequate information.

In most cases, the Commissioner will make any necessary request for additional information within 30 days after the original submission. However, in certain cases, the Commissioner may have to request additional information after the initial 30-day period. The Commissioner must retain this option to ensure that he obtains the information that is necessary to make a proper decision on a premarket notification. Therefore, the Commissioner rejects the comment that suggested that the regulation should require the Commissioner to request any necessary additional information within 30 days after the initial submission.

After the Commissioner requests additional information and the information is submitted, the amended premarket notification will receive expedited review and FDA will generally respond to it in far less than 90 days. However, in certain cases, the additional information may be substantial and a 90-day period may be needed to review this information. The Commissioner therefore rejects any suggestion that FDA should allow the device to be marketed less than 90 days after the submission of the additional information.

If possible the Commissioner will notify the person submitting the premarket notification of the specific information required to complete the submission. However, in some cases, this may not be possible. The Commissioner believes that the manufacturer is best qualified to show whether his product is substantially equivalent to one already on the market. The Commissioner therefore rejects the suggestion that the regulation require the Commissioner to specify exactly what information is lacking in a premarket notification submission. However, the Commissioner will provide this information to the applicant, where appropriate.

The Commissioner is adding a requirement to new § 807.87(h) stating that, if the additional information is not submitted within 30 days after it is requested, the Commissioner will consider the premarket notification submission to be withdrawn. In such cases, the device cannot be marketed unless (1) a new premarket notification is submitted and the device is declared substantially equivalent, or (2) the device is classified in class I or II pursuant to a petition filed under section 513(f)(2) of the act, or (3) the device is the subject of an approved premarket approval application under section 515 of the act.

28. The Commissioner has revised § 807.95(a) to clarify that in all cases the existence of a premarket notification submission is to be available for public disclosure upon request when a device is marketed or the manufacturer or distributor discloses his intent to market the device. This is true whether any period for confidentiality that FDA granted the notification has expired and whether the premarket notification was submitted before or after the effective date of these regulations.

The proposal did not address the possibility that the person submitting a premarket notification submission might disclose his intent to market the device, not did the proposal indicate whether FDA would respond to public information requests about whether there had been a submission for an already marketed or advertised product. The agency has no grounds for withholding information that would reveal the intent to market a device when the person submitting the premarket notification submission has revealed these marketing plans, or when marketing has already occurred. There may be instances in which a manufacturer seeks to discover whether a competitor has violated the act, by determining whether there is a premarket notification submission for a device. However, the fact that a manufacturer has not submitted such a notification is not confidential commercial information that is exempt from disclosure, however useful or interesting it might be. Handling of public information requests for premarket notification submissions is facilitated when those requests are accompanied by evidence that there has been public disclosure of the intent to market a device, or that marketing is begun, or when FDA has obtained such evidence from other sources.

The Commissioner also has clarified in § 807.95(c) the duration of confidentiality for premarket notification submissions in the three situations where submissions may be granted confidential treatment for more than 90 days. Of course, none of these provisions for continued confidentiality apply once the device is marketed or the person who submitted the premarket notification has revealed the intent to market the device.

First, if the Commissioner requests additional information regarding the device under § 807.87(h), the existence of the submissions will not be disclosed until 90 days after the agency's receipt of a complete premarket notification submission.

Second, if the Commissioner determines that the device is a class III device, it cannot be marketed without premarket approval or reclassification. When the Commissioner makes this determination, the existence of the submission will not be disclosed unless a petition for reclassification is submitted under section 513(f) of the act and its existence can be disclosed under proposed § 860.5(d). Proposed § 860.5(d) is a provision of the agency's classification regulations to be published in the FEDERAL REGISTER in the near future, and is consistent with the requirements in section 513(f)(2) of the act that FDA

provide opportunity for public participation in reclassification of new devices and in section 520(c) of the act that FDA not rely on trade secrets or other confidential commercial information as the basis for reclassifying a class III device. Future FDA regulations will address the confidentiality of intent to market a device when an application for premarket approval of a device is submitted under section 515 of the act. The Commissioner believes that it will be very unlikely that the intent to market a device that is the subject of such an application would in fact be confidential, because the sponsor would almost invariably have had to reveal its marketing plans to some persons outside the company and because of the statutory requirement for advisory committee review.

Third, if the person requests, and FDA agrees, that the intent to market a device be held in confidence for more than 90 days because the person has reason to believe that the actual marketing of the device may be delayed, the Commissioner will not disclose the existence of the submission until FDA receives the required notification that the device has been put on the market or that the intent to market the device has been disclosed.

Once FDA can disclose the fact that a premarket notification submission exists, the contents of the submission (other than information protected under § 807.95(d)) will be available for public disclosure.

29. Several comments asserted that the intent to market a device should be kept confidential without the owner or operator having to request confidentiality as required by proposed § 807.95(a). The Commissioner believes that it is appropriate to require the person submitting the premarket notification submission to request that it be kept confidential. The intent to market a device will in many cases be known to persons outside the company, and the Commissioner believes that information concerning a premarket notification submission, including its existence, should be available for public disclosure, upon request, unless the person submitting it shows that the intent to market the device is confidential commercial information.

The Commissioner has revised § 807.95 to require a person submitting a certification of confidentiality to include a statement that the person understands that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q). This change underlies the importance of submitting truthful requests for confidential treatment of premarket notification submissions and thus discourages indiscriminate claims of confidentiality. The Commissioner also is requiring the person submitting the request for confidentiality to agree to notify FDA immediately if the person discloses the intent to market the device to anyone, except employees of or paid consultants to the establishment, or individuals in an advertising or law firm pursuant to commercial arrangements with appropriate safeguards for confidentiality.

30. Another comment stated that the intent to market a device should be kept confidential until the owner or operator notifies FDA of the actual marketing of the device.

The regulations have retained the provision that the existence of the premarket notification submission, and thus the contents other than trade secrets, will be kept confidential for 90 days when the person submitting it demonstrates to the agency's satisfaction that the intent to market the device is confidential. The agency believes this approach is more workable in most cases than that suggested by the comment. However, under § 807.95(b)(1)(iii) the Commissioner will keep the intent to market a device confidential until actual marketing of the device begins when this is expected to occur more than 90 days after the premarket notification if the person submitting it convinces FDA that the notification should be kept confidential until actual marketing begins and agrees to comply with certain specified conditions, including a requirement to notify the Commissioner when the device is marketed or when the person reveals the intent to market the device.

31. Other comments opposed the conditions placed on persons seeking to protect the confidentiality of a premarket notification submission. Several comments objected to the fact that proposed § 807.95 required the owner or operator to certify that he has not released the information to individuals outside the company who are not paid consultants. These comments pointed out that the owner or operator may have to release the information to investigators and scientists who are not paid. The comments also stated that the intent to market a device should be kept confidential by FDA if the intent to market is made known to individuals not in the employ of the owner or operator but who are in a confidential relationship with him and if the manufacturer has taken reasonable steps to protect the confidentiality of the information. One comment stated that the intent to market a device may necessarily be released on a confidential basis to advertising personnel and others who do not fall within the category of employees of the establishment under proposed § 807.95(a)(1) but should nevertheless be kept confidential.

The Commissioner agrees that a discussion with individuals in an advertising firm or a law firm should not be regarded as a breach of confidentiality of the intent to market a device and has revised the regulation accordingly.

32. One comment stated that material dealing with comparative literature and data to support a claim of substantial equivalence should be exempt from disclosure because it could be relevant in the event there is litigation involving patent infringement.

Under § 807.95(d), data and information submitted pursuant to the premarket notification regulations that are trade secret information shall be held as confidential. The Commissioner cannot, however, make a broad statement that all material dealing with comparative literature and data to support substantial equivalence will be considered confidential. The possibility that such information could be relevant in litigation involving patent infringement does not provide FDA with grounds for withholding the information under any exemption to the Freedom of Information Act. Although evidence that a competitor infringed a patent may be commercially useful information, it is not confidential commercial information that is entitled to confidentiality. The Commissioner notes, however, that a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act relates to the fact that the product can lawfully be marketed without premarket approval or reclassification. This determination is not intended to have any bearing whatever on the resolution of patent infringement suits.

33. The Commissioner cautions that FDA may in the future propose revisions in the policy set forth in § 807.95. FDA currently is reviewing the procedures by which it handles requests for disclosure of information concerning the existence of a variety of submissions that are made to it, including new drug applications, new animal drug applications, and device premarket approval applications. The agency may revise its current procedures so as to acknowledge in all cases the existence of these pending submissions. Because the proper method of handling requests for data and information on device premarket notification submissions involves many of the same issues that are involved in requests for information on new drug applications and similar applications, § 807.95 may eventually be revised in future regulations in light of the agency's decisions on how all such related submissions should be handled.

The Commissioner has had to decide how to handle public information requests for premarket notification submissions received before the effective date of these regulations. Freedom of information requests have been received for such premarket notification submissions review by FDA. There is no question about the agency's handling of these requests where FDA knows, either from the public information requests or from other sources, that the device has been put on the market or the intent to do so has been disclosed: The existence of the notification and its contents, other than any bona fide trade secrets, are disclosable. More difficult questions arise in situations in which FDA simply does not know whether a device that was the subject of a submission has been put on the market or the intent to do so has been disclosed. Therefore, as discussed below, FDA is requiring, by October 25, 1977, submission of justification for continued confidential treatment for most premarket approval notifications re-

ceived before the effective date of the regulation.

The following describes how FDA is dealing with requests concerning premarket notification submissions received before September 22, 1977, the effective date of the regulations:

a. The existence of the premarket notification submission and its contents, other than bona fide trade secrets, shall be available for public disclosure if the device has been marketed or if the intent to market the device has been disclosed.

b. During the 90 days after the submission of a premarket notification submission, FDA will treat the existence of the submission and its contents as confidential unless the agency has information that the device has been marketed or the intent to market the device has been disclosed.

c. If the submission indicated that marketing was not expected for more than 90 days, and requested confidential treatment until marketing began, and included an agreement to notify FDA when marketing began, FDA will treat the existence of the submission and its contents as confidential unless the agency has information that the device has been marketed or the intent to do so has been disclosed. If much time has elapsed since the expiration of the 90-day notification period, FDA will make reasonable efforts to determine whether a device which was the subject of a submission has been put on the market or the intent to market the device has been disclosed.

d. Any premarket notification submission received before the effective date of the regulations shall be available for public disclosure 90 days after its receipt by FDA except to the extent that the person who submitted the submission demonstrates by October 21, 1977, that the existence of the submission and its contents are still entitled to confidentiality. Where the FDA receives a public information request for a submission more than 90 days after the submission's receipt, but before October 21, 1977, FDA will make reasonable efforts to determine whether the device has been put on the market or the intent to market the device has been disclosed. A person who seeks to demonstrate that the existence of a submission is still confidential should submit the necessary documentation to the Food and Drug Administration, Bureau of Medical Devices (HFK-20), 8757 Georgia Ave., Silver Spring, Md. 20910. This documentation should indicate whether the device has not been marketed or the intent to do has not been disclosed except to employees of or paid consultants to the establishment, or to individuals in an advertising or law firm pursuant to commercial arrangements with appropriate safeguards for secrecy.

e. Where a public information request is made concerning a premarket notification submission and there is no submission or there is a submission whose existence is confidential under b, c, or d above, FDA will respond to the request by indicating that no submission described in the request has been received that is disclosable, and that FDA cannot indicate whether a submission has been received.

f. To determine whether the intent to market a device has been disclosed, FDA is applying the rules in § 807.95.

Therefore, under the Federal Food, Drug and Cosmetic Act (secs. 301(p), 501, 502, 510, 701(a), 52 Stat. 1049–1051 as amended, 1055, 86 Stat. 562, 90 Stat. 576–580 (21 U.S.C. 331(p), 351, 352, 360, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner is amending Chapter I of Title 21 of the Code of Federal Regulations as follows:

PART 20—PUBLIC INFORMATION

1. By amending § 20.100 by redesignating paragraph (c)(28) as paragraph (c)(29). As revised, paragraph (c)(28) and (29) reads as follows:

§ 20.100 Applicability; cross reference to other regulations.

* * * * *

(c) * * *

(28) Device premarket notification submissions, in § 807.95 of this chapter.

(29) Electronic product information, in §§ 1002.4 and 1002.42 of this chapter.

2. By revising § 20.116 to read as follows:

§ 20.116 Drug and device listing information.

Information submitted to the Food and Drug Administration pursuant to section 510 (a)–(j) of the act shall be subject only to the special disclosure provisions established in §§ 207.37 and 807.37 of this chapter.

PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

3. By amending § 25.1 in paragraph (d), by revising paragraph (d)(4) and (5) and adding new paragraph (d)(6), to read as follows:

§ 25.1 Applicability.

* * * * *

(d) * * *

(4) Issuance or amendment of food standards;

(5) Investigational new drug applications and investigational new animal drug applications, unless the agency notifies the applicant that one is required; and

(6) Device premarket notifications submissions.

* * * * *

PART 807—ESTABLISHMENT REGISTRATION FOR MANUFACTURERS OF DEVICES

4. By adding new Part 807 to read as follows:

Subpart A—General Provisions

Sec.
807.3 Definitions.

Subpart B—Procedures for Domestic Device Establishments

807.20 Who must register.
807.21 Times for establishment registration.
807.22 How and where to register establishments.
807.25 Information required or requested for establishment registration.
807.26 Amendments to establishment registration.
807.35 Notification of registrant.
807.37 Inspection of establishment registrations.
807.39 Misbranding by reference to establishment registration or to registration number.

Subpart C—Registration Procedures for Foreign Device Establishments

807.40 Establishment registration for foreign manufacturers of devices.

Subpart D—Exemptions

Sec.
807.65 Exemption for device establishments.

Subpart E—Premarket Notification Procedures

807.81 When a premarket notification submission is required.
807.85 Exemption from premarket notification.
807.87 Information required in a premarket notification submission.
807.90 Format of a premarket notification submission.
807.95 Confidentiality of information.
807.97 Misbranding by reference to premarket notification.

AUTHORITY: Secs. 301(p), 501, 502, 510, 701(a), 52 Stat. 1049–1051 as amended, 1055, 76 Stat. 794 as amended, 86 Stat. 562 as amended, 90 Stat. 576–580 (21 U.S.C. 331(p), 351, 352, 360, 371(a)).

Subpart A—General Provisions

§ 807.3 Definitions.

(a) "Act" means the Federal Food, Drug, and Cosmetic Act.

(b) "Commercial distribution" means any distribution of a device intended for human use which is held or offered for sale but does not include the following:

(1) Internal or interplant transfer of a device between establishments within the same parent, subsidiary, and/or affiliate company;

(2) Any distribution of a device intended for human use which has in effect an approved exemption for investigational use pursuant to section 520(g) of the act and Part 812 of this chapter; or

(3) Any distribution of a device, before the effective date of Part 812 of this chapter, that was not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and that is classified into class III under section 513(f) of the act: *Provided,* That the device is intended solely for investigational use, and under section 501(f)(2)(A) of the act the device is not required to have an approved premarket approval application as provided in section 515 of the act.

(c) "Establishment" means a place of business under one management at one general physical location at which a device is manufactured, assembled, or otherwise processed.

(d) "Manufacture, preparation, propagation, compounding, assembly, or processing" of a device means the making by chemical, physical, biological, or other procedures of any article that meets the definition of device in section 201(h) of the act. These terms include the following activities:

(1) Repackaging or otherwise changing the container, wrapper, or labeling of any device package in furtherance of the distribution of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer;

(2) Initial distribution of imported devices; or

(3) Initiation of specifications for devices that are manufactured by a second party for subsequent commercial distribution by the person initiating specifications.

(e) "Official correspondent" means the person designated by the owner or oper-

ator of an establishment as responsible for the following:

(1) The annual registration of the establishment;

(2) Contact with the Food and Drug Administration for device listing;

(3) Maintenance and submission of a current list of officers and directors to the Food and Drug Administration upon the request of the Commissioner; and

(4) The receipt of pertinent correspondence from the Food and Drug Administration directed to and involving the owner or operator and/or any of the firm's establishments.

(f) "Owner or operator" means the corporation, subsidiary, affiliated company, partnership, or proprietor directly responsible for the activities of the registering establishment.

(g) "Distributor" means any person who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package.

(h) Any term defined in section 201 of the act shall have that meaning.

Subpart B—Procedures for Domestic Device Establishments

§ 807.20 Who must register.

(a) Any owner or operator of an establishment not exempt under section 510 (g) of the act or Subpart D of this part who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use is required to register. The term device includes all in vitro diagnostic products and in vitro diagnostic biological products not subject to licensing under section 351 of the Public Health Service Act. Such owner or operator is required to register his name, places of business, and all such establishments whether or not the output of such establishments enter interstate commerce. The registration requirements shall pertain to any person who:

(1) Initiates or develops specifications for a device that is to be manufactured by a second party for commercial distribution by the person initiating specifications;

(2) Manufactures for commercial distribution a device either for himself or for another person;

(3) Repackages or relabels a device;

(4) Initially distributes a device imported into the United States; or

(5) Manufactures components or accessories which are ready to be used for any intended health-related purpose and are packaged or labeled for commercial distribution for such health-related purpose, e.g., blood filters, hemodialysis tubing, or devices which of necessity must be further processed by a licensed practitioner or other qualified person to meet the needs of a particular patient, e.g., a manufacturer of ophthalmic lens blanks.

(b) No registration fee is required. Registration does not constitute an admission of agreement or determination that a product is a "device" within the meaning of section 201(h) of the act.

§ 807.21 Times for establishment registration.

The owner or operator of an establishment entering into, or currently engaged in, an operation defined in § 807.3 (c) and not currently registered shall register the establishment by September 22, 1977. The owner or operator of an establishment who has not previously entered into an operation defined in § 807.3 (c) shall register within 30 days after entering into such an operation. Owners or operators of all establishments shall update their registration information annually between November 15 and December 31.

§ 807.22 How and where to register establishments.

The first registration of a device establishment shall be on Form FD–2891 (Initial Registration of Device Establishment). Forms are obtainable on request from the Department of Health, Education, and Welfare, Food and Drug Administration, Bureau of Medical Devices (HFK–124), 8757 Georgia Ave., Silver Spring, MD 20910, or from the Food and Drug Administration district offices. Subsequent annual registration shall be accomplished on Form FD–2891 (a) (Registration of Device Establishment) which will be furnished by the Food and Drug Administration before November 15 of each year to establishments whose registration for that year was validated pursuant to § 807.35(a). The completed form shall be mailed to the above address before December 31 of that year.

§ 807.25 Information required or requested for establishment registration.

(a) Form FD–2891 and Form FD–2891 (a) are the approved forms for initially providing the information required by the act and for providing annual registration, respectively. The required information includes the name and street address of the device establishment, including post office ZIP Code, all trade names used by the establishment, and the business trading name of the owner or operator of such establishment.

(b) The owner or operator shall identify the device activities of the establishment such as manufacturing, repackaging, or distributing of imported devices and identify any other FDA registries in which the establishment is registered.

(c) Each owner or operator is required to maintain a listing of all officers, directors, and partners for each establishment he registers and to furnish this information to the Food and Drug Administration upon request.

(d) Each owner or operator shall provide the name of an official correspondent who will serve as a point of contact between the Food and Drug Administration and the establishment for matters relating to the registration of device establishments and the listing of device products. All future correspondence relating to registration, including requests for the names of partners, officers, and directors, will be directed to this official correspondent. In the event no person is designated by the owner or operator, the owner or operator of the establishment will be the official correspondent.

(e) The designation of an official correspondent does not in any manner affect the liability of the owner or operator of the establishment or any other individual under section 301(p) or any other provision of the act.

§ 807.26 Amendments to establishment registration.

Changes in individual ownership, corporate or partnership structure, or location of an operation defined in § 807.3(c) shall be submitted on Form FD–2891(a). This information shall be submitted within 30 days of such changes. Changes in the names of officers and/or directors of the corporation(s) shall be filed with the establishment's official correspondent and shall be provided to the Food and Drug Administration upon receipt of a written request for this information.

§ 807.35 Notification of registrant.

(a) The Commissioner will provide to the official correspondent, at the address listed on the form, a validated copy of Form FD–2891 or Form FD–2891(a) (whichever is applicable) as evidence of registration. A permanent registration number will be assigned to each device establishment registered in accordance with these regulations.

(b) Owners and operators of device establishments who also manufacture or process blood or drug products at the same establishment shall also register with the Bureau of Biologics and Bureau of Drugs, as appropriate. Blood products shall be listed with the Bureau of Biologics, Food and Drug Administration, pursuant to Part 607 of this chapter; drug products shall be listed with the Bureau of Drugs, Food and Drug Administration, pursuant to Part 207 of this chapter.

(c) Although establishment registration is required to engage in the device activities described in § 807.20, validation of registration in itself does not establish that the holder of the registration is legally qualified to deal in such devices and does not represent a determination by the Food and Drug Administration as to the status of any device.

§ 807.37 Inspection of establishment registrations.

A copy of the Form FD–2891 and FD–2891(a), filed by the registrant, will be available for inspection pursuant to § 510(f) of the act, at the Department of Health, Education, and Welfare, Food and Drug Administration, Bureau of Medical Devices (HFK–124), 8757 Georgia Ave., Silver Spring, MD 20910. In addition, there will be available for inspection at each of the Food and Drug Administration district offices the same information for firms within the geographical area of such district office.

Upon request and receipt of a self-addressed stamped envelope, verification of registration number or location of a registered establishment will be provided.

§ 807.39 Misbranding by reference to establishment registration or to registration number.

Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding.

Subpart C—Registration Procedures for Foreign Device Establishments

§ 807.40 Establishment registration for foreign manufacturers of devices.

Foreign device establishments that export devices into the United States are requested to register in accordance with the procedures of Subpart B of this part, unless exempt under Subpart D of this part.

Subpart D—Exemptions

§ 807.65 Exemptions for device establishments.

The following classes of persons are exempt from registration in accordance with § 807.20 under the provisions of section 510(g) (1), (2), and (3) of the act, or because the Commissioner has found, under section 510(g)(4) of the act, that such registration is not necessary for the protection of the public health:

(a) A manufacturer of raw materials or components to be used in the manufacture or assembly of a device who would otherwise not be required to register under the provisions of this part.

(b) A manufacturer of devices to be used solely for veterinary purposes.

(c) A manufacturer of general purpose articles such as chemical reagents or laboratory equipment whose uses are generally known by persons trained in their use and which are not labeled or promoted for medical uses.

(d) Licensed practitioners, including physicians, dentists, and optometrists, who manufacture or otherwise alter devices solely for use in their practice.

(e) Pharmacies, surgical supply outlets, or other similar retail establishments dispensing or selling devices in the regular course of business at the retail level. This exemption also applies to a pharmacy or other similar retail establishment that purchases a device for subsequent distribution under its own name, e.g., a properly labeled health aid such as an elastic bandage or crutch, indicating "distributed by" or "manufactured for" followed by the name of the pharmacy.

(f) Persons who manufacture, prepare, propagate, compound, or process devices solely for use in research, teaching, or analysis and do not introduce such devices into commercial distribution.

(g) Persons who handle devices but make no revisions to such devices or their immediate containers, such as wholesalers or warehousers.

(h) Carriers by reason of their receipt, carriage, holding or delivery of devices in the usual course of business as carriers.

(i) Persons who dispense devices to the ultimate consumer or whose major responsibility is to render a service necessary to provide the consumer (i.e., patient, physician, layman, etc.) with a device or the benefits to be derived from the use of a device; for example, a hearing aid dispenser, optician, clinical laboratory, assembler of diagnostic X-ray systems, and personnel from a hospital, clinic, dental laboratory, orthotic or prosthetic retail facility, whose primary responsibility to the ultimate consumer is to dispense or provide a service through the use of a previously manufactured device.

Subpart E—Premarket Notification Procedures

§ 807.81 When a premarket notification submission is required.

Except as provided in paragraph (b) of this section, each person who is required to register his establishment pursuant to § 807.20 must submit a premarket notification submission to the Food and Drug Administration at least 90 days before he proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use which meets any of the following criteria:

(1) The device is being introduced into commercial distribution for the first time; that is the device is not of the same type as, or is not substantially equivalent to, (i) a device in commercial distribution before May 28, 1976, or (ii) a device introduced for commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II.

(2) The device is being introduced into commercial distribution for the first time by a person required to register, whether or not the device meets the criteria in paragraph (a)(1) of this section.

(3) The device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use. The following constitute significant changes or modifications that require a premarket notification:

(i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process.

(ii) A major change or modification in the intended use of the device.

(b) A premarket notification under this subpart is not required for a device for which a premarket approval application under section 515 of the act, or for which a petition to reclassify under section 513(f)(2) of the act, is pending before the Food and Drug Administration.

(c) In addition to complying with the requirements of this part, owners or operators of device establishments that manufacture radiation-emitting electronic products, as defined in § 1000.3 of this chapter, shall comply with the reporting requirements of Part 1002 of this chapter.

§ 807.85 Exemption from premarket notification.

(a) A device is exempt from the premarket notification requirements of this subpart if the device intended for introduction into commercial distribution is not generally available in finished form for purchase and is not offered through labeling or advertising by the manufacturer, importer, or distributor thereof for commercial distribution, and the device meets one of the following conditions:

(1) It is intended for use by a patient named in the order of the physician or dentist (or other specially qualified person); or

(2) It is intended solely for use by a physician or dentist (or other specially qualified person) and is not generally available to, or generally used by, other physicians or dentists (or other specially qualified persons).

(b) A distributor who places a device into commercial distribution for the first time under his own name and a repackager who places his own name on a device and does not change any other labeling or otherwise affect the device shall be exempted from the premarket notification requirements of this subpart if:

(1) The device was in commercial distribution before May 28, 1976; or

(2) A premarket notification submission was filed by another person.

§ 807.87 Information required in a premarket notification submission.

Each premarket notification submission shall contain the following information:

(a) The device name, including both the trade or proprietary name and the common or usual name or classification name of the device.

(b) The establishment registration number, if applicable, of the owner or operator submitting the premarket notification submission.

(c) The class in which the device has been put under section 513 of the act and, if known, its appropriate panel; or, if the owner or operator determines that the device has not been classified under such section, a statement of that determination and the basis for the person's determination that the device is not so classified.

(d) Action taken by the person required to register to comply with the requirements of the act under section 514 for performance standards.

(e) Proposed labels, labeling, and advertisements sufficient to describe the

device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied.

(f) A statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement. This information may include an identification of similar products, materials, design and considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device.

(g) Where a person required to register intends to introduce into commercial distribution a device that has undergone a significant change or modification that could significantly affect the safety or effectiveness of the device, or the device is to be marketed for a new or different indication for use, the premarket notification submission must include appropriate supporting data to show that the manufacturer has considered what consequences and effects the change or modification or new use might have on the safety and effectiveness of the device.

(h) Any additional information regarding the device requested by the Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution. A request for additional information will advise the owner or operator that there is insufficient information contained in the original premarket notification submission for the Commissioner to make this determination and that the owner or operator may either submit the requested data or a new premarket notification containing the requested information at least 90 days before the owner or operator intends to market the device, or submit a premarket approval application in accordance with section 515 of the act. If the additional information is not submitted within 30 days following the date of the request, the Commissioner will consider the premarket notification to be withdrawn.

§ 807.90 Format of a premarket notification submission.

Each premarket notification submission pursuant to this part shall be submitted in accordance with this section. Each submission shall:

(a) Be addressed to the Food and Drug Administration, Bureau of Medical Devices (HFK–20), 8757 Georgia Ave., Silver Spring, Md. 20910. All inquiries regarding a premarket notification submission should be in writing and sent to the above address.

(b) Be bound into a volume or volumes, where necessary.

(c) Be submitted in duplicate on standard size paper, including the original and two copies of the cover letter.

(d) Be submitted separately for each product the manufacturer intends to market.

(e) Designated "510(k) Notification" in the cover letter.

§ 807.95 Confidentiality of information.

(a) The Food and Drug Administration will disclose publicly whether there exists a premarket notification submission under this part:

(1) Where the device is on the market, i.e., introduced or delivered for introduction into interstate commerce for commercial distribution;

(2) Where the person submitting the premarket notification submission has disclosed, through advertising or any other manner, his intent to market the device to scientists, market analysts, exporters, or other individuals who are not employees of, or paid consultants to, the establishment and who are not in an advertising or law firm pursuant to commercial arrangements with appropriate safeguards for secrecy; or

(3) Where the device is not on the market and the intent to market the device has not been so disclosed, except where the submission is subject to an exception under paragraph (b) or (c) of this section.

(b) The Food and Drug Administration will not disclose publicly the existence of a premarket notification submission for a device that is not on the market and where the intent to market the device has not been disclosed for 90 days from the date of receipt of the submission, if:

(1) The person submitting the premarket notification submission requests in the submission that the Food and Drug Administration hold as confidential commercial information the intent to market the device and submits a written certification to the Commissioner:

(i) That the person considers his intent to market the device to be confidential commercial information;

(ii) That neither the person nor, to the best of his knowledge, anyone else, has disclosed through advertising or any other manner, his intent to market the device to scientists, market analysts, exporters, or other individuals, except employees of, or paid consultants to, the establishment or individuals in an advertising or law firm pursuant to commercial arrangements with appropriate safeguards for secrecy;

(iii) That the person will immediately notify the Food and Drug Administration if he discloses the intent to market the device to anyone, except employees of, or paid consultants to, the establishment or individuals in an advertising or law firm pursuant to commercial arrangements with appropriate safeguards for secrecy;

(iv) That the person has taken precautions to protect the confidentiality of the intent to market the device; and

(v) That the person understands that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q); and

(2) The Commissioner agrees that the intent to market the device is confidential commercial information.

(c) Where the Commissioner determines that the person has complied with the procedures described in paragraph (b) of this section with respect to a device that is not on the market and where the intent to market the device has not been disclosed, and the Commissioner agrees that the intent to market the device is confidential commercial information, the Commissioner will not disclose the existence of the submission for 90 days from the date of its receipt by the agency. In addition, the Commissioner will continue not to disclose the existence of such a submission for the device for an additional time when any of the following occurs:

(1) The Commissioner requests in writing additional information regarding the device pursuant to § 807.87(g), in which case the Commissioner will not disclose the existence of the submission until 90 days after the Food and Drug Administration's receipt of a complete premarket notification submission;

(2) The Commissioner determines that the device intended to be introduced is a class III device and cannot be marketed without premarket approval or reclassification, in which case the Commissioner will not disclose the existence of the submission unless a petition for reclassification is submitted under section 513(f)(2) of the act and its existence can be disclosed under § 860.5(d) of this chapter; or

(3) The person has requested in the premarket notification submission that the Commissioner protect the confidentiality of the intent to market a device for more than 90 days from the date of receipt of the premarket notification submission by the Food and Drug Administration, and the Commissioner determines that the person has reason to believe that the actual introduction of the device to the market may take longer than 90 days, and the person agrees in a written certification to provide the Commissioner with written notification immediately if the device is put on the market or the intent to market is disclosed. In this case the Commissioner will not disclose the existence of the submission until the Food and Drug Administration's receipt of notification by the person that the device has been put on the market or that the intent to market the device has been disclosed.

(d) Data or information submitted with, or incorporated by reference in, a premarket notification submission (other than safety and effectiveness data that have not been disclosed to the public) shall be available for disclosure by the Food and Drug Administration when the intent to market the device is no longer confidential in accordance with this section, unless exempt from public disclosure in accordance with Part 20 of this chapter. Upon final classification, data and information relating to safety and effectiveness of a device classified in class I (general controls) or class II (performance standards) shall be available for public disclosure. Data and information relating to safety and effectiveness of a device classified in class III

(premarket approval) that have not been released to the public shall be retained as confidential unless such data and information become available for release to the public under § 860.5(d) or other provisions of this chapter.

§ 807.97 Misbranding by reference to premarket notification.

Submission of a premarket notification in accordance with this subpart, and a subsequent determination by the Commissioner that the device intended for introduction into commercial distribution is substantially equivalent to a device in commercial distribution before May 28, 1976, or is substantially equivalent to a device introduced into commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II, does not in any way denote official approval of the device. Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding.

PART 809—IN VITRO DIAGNOSTIC PRODUCTS FOR HUMAN USE

§ 809.20 [Amended]

2. In Part 809, § 809.20 *General requirements for manufacturers and producers of in vitro diagnostic products* is amended by deleting paragraph (a) and designating it "reserved."

Effective date: This regulation shall be effective September 22, 1977.

(Secs. 301(p), 501, 502, 510, 701(a), 52 Stat. 1049–1051 as amended, 1055, 76 Stat. 794 as amended, 86 Stat. 562 as amended, 90 Stat. 576–580 (21 U.S.C. 331(p), 351, 352, 360, 371(a)).)

Dated: August 12, 1977.

DONALD KENNEDY,
Commissioner of Food and Drugs.

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